AUG 30 1999

GE Medical Systems

General Electric Company
PO Box 414, Milwaukee, WI 53201

K992066

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Pat 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (414) 544-3894
Summary prepared: June 15, 1999

Identification of Product: Revolution TX/i Digital Radiographic Table System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53118

Marketed Devices: Digital detector (part of Digital Radiographic Imaging System, renamed Revolution XQ/i system) (K982196); SCX (Advantx) radiographic system (K862120); Ultranet-SA Collimator (K894142); Maxiray 100 Radiographic Tube (Pre-amendment); SCPU Generator (K940277) and SG100 vertical bucky stand (Pre-amendment).

Device Description: The Revolution TX/i Digital Radiographic Table System is designed to perform radiographic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing and storage. The Revolution TX/i Digital Radiographic Table System consists of a an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, collimator, system controller, and generator. A separate, conventional SG100 vertical bucky stand is provided for chest or other general purpose radiographic procedures.

Indications for Use: The Revolution TX/i Digital Radiographic Table System is indicated for use in generating radiographic images of human anatomy. It is intended to replace

radiographic film / screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with Predicate: The Revolution TX/i Digital Radiographic Table System is substantially equivalent to the Revolution XQ/i system, originally cleared as Digital Radiographic Imaging System in 510(k) K982196. The table used in the Digital Radiographic Table System is substantially equivalent to the Compax 40E table cleared in 510(k) K884930.

Summary of Studies: The device has the same detector and acquisition system as the predicate device, and the same intended uses. It will be evaluated for conformance with UL and IEC safety standards. We consider the device to be substantially equivalent to the predicate device.

Conclusions: GE considers the Revolution TX/i Digital Radiographic Table System to be equivalent with the predicate device. The TX/i Digital Radiographic Table System provides radiographic images that result in equivalent or better diagnostic capabilities than film / screen images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- A Hazard Analysis
- A Software Development and Validation Process
- Certification to applicable UL and IEC safety standards
- External evaluations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 1999

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
General Electric Company
P.O. Box 414
Milwaukee, WI 53201

Re: K992066
Revolution TX/I Digital Radiographic
Table System
Dated: June 17, 1999
Received: June 18, 1999
Product Code: 90 KPR & MQB
Regulatory Class: II (two)
21 CFR 892.1680 & 892.1630

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K992066

Device Name: Revolution TX/i Digital Radiographic Table System

Indications for Use

The Revolution TX/i Digital Radiographic Table System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992066